IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
GREENSBORO DIVISION

LLOYD BELL, Individually and As Executor of the Estate of BETTY WHITLEY BELL, Deceased, Plaintiff, v. AMERICAN INTERNATIONAL INDUSTRIES, et al., Defendants.	)	CASE NO. 1:17-CV-00111

NORTHWELL HEALTH, INC.'S REPLY IN SUPPORT OF
OBJECTIONS TO AND APPEAL FROM THE MAGISTRATE JUDGE'S ORDER

Remarkably, despite liberal use of 6,132 words and a 190 page filing, Defendant American International Industries' ("AII") Response fails to address the heart of Northwell Health, Inc.'s ("Northwell") Objections to the Magistrate Judge's Order ("Objections"): the Order is clearly erroneous because the Federal Policy for the Protection of Human Subjects, 45 C.F.R. Part 46, Subpart A (or, "Common Rule") and firmly established Institutional Review Board ("IRB") principles demand that Plaintiff's expert, Jaqueline Moline, M.D. ("Dr. Moline"), not be forced to unmask the identities of individuals, including Betty Whitley Bell ("Plaintiff"), who were participants in a Northwell IRB-approved research study ("Research Study").[1] Northwell's Motion seeks a limited and narrowly tailored extension of the protective order entered on September 25, 2020 ("Protective Order") to provide this critical protection. Northwell does not

[1] Northwell encompasses Dr. Moline's peer-reviewed article in this reference.

seek to preclude AII from questioning Dr. Moline about Plaintiff, nor does Northwell seek to preclude AII from questioning Dr. Moline about the Research Study.

For the reasons set forth below, AII's arguments as to the alleged mootness and untimeliness of Northwell's Motion are equally unavailing. The Court should overturn the Magistrate Judge's Order, grant Northwell's Motion to Intervene, and extend the Protective Order.

ARGUMENT

I. The Magistrate Judge's Order Denying Northwell's Motion to Intervene ("Motion") Was Clearly Erroneous

A. Northwell's Motion Is Not Moot

Both the Magistrate Judge and AII have stated that, because Plaintiff did not present Dr. Moline for deposition by January 7, 2021, Northwell's Motion is no longer a live issue. ECF No. 309, at 3; ECF No. 331, at 19-20. This position is belied by the recent filings in this case. The parties' Joint Status Report filed on March 5, 2021 makes clear that Plaintiff intends to move for leave to present Dr. Moline for deposition, and the Magistrate Judge and AII erroneously disregarded this fact. ECF No. 312, at 11.

Whether or not Plaintiff will be successful in such a motion is not pertinent to Northwell's objections. Nor is there any burden on the part of Northwell to demonstrate "excusable neglect" or any other standard on behalf of Plaintiff, given that Plaintiff did not offer Dr. Moline for deposition on January 7, 2021. ECF No. 252. Northwell has no control over whether Plaintiff ultimately seeks to call Dr. Moline as a witness. However, Northwell's interest in filing its Objections is to ensure that representations made as part of its IRB review regarding the confidentiality of research studies are upheld and will not be lost through disclosure during the course of this litigation.

The question of whether Dr. Moline will ultimately testify in this litigation remains unresolved. So long as there is no finality with respect to that issue, Northwell's confidentiality concerns are not moot.

B. Northwell's Motion is Not Untimely, Duplicative, or Prejudicial

In support of alleged untimeliness surrounding the Motion, both the Magistrate Judge and AII maintain that there was a "delay" between the issuance of a subpoena on Northwell and Northwell's Motion to Intervene. ECF No. 309, at 4-5; ECF No. 331, at 20-22. Neither Northwell nor the parties dispute the timeline. However, asserting that this timeline was somehow prejudicial to Defendants is unsupported by the facts, and AII has failed to articulate any true prejudice.

The lack of prejudice is clear given that the alleged delay in intervention has not stalled the progression of the case. Critically, expert witness discovery is ongoing, as various related motions are unresolved, and expert deposition deadlines may extend to April 27, 2021 or beyond. ECF No. 280. Since Northwell filed its Motion in December 2020, the trial date in this case has been rescheduled to October 4, 2021. Northwell is not aware of any reason why its intervention concerning the narrow extension of the Protective Order would cause credible delay, or otherwise "unfairly disrupt … resolution of [this] case." *Wright v. Krispy Kreme Doughnuts, Inc.*, 231 F.R.D. 475, 478 (M.D.N.C. 2005). Tellingly, neither the Magistrate Judge's Order nor AII's brief points to any specific basis for prejudice surrounding timing in light of the ongoing expert discovery and the delayed trial date.

Northwell's Motion is also not duplicative of Plaintiff's earlier arguments in this matter, contrary to the Magistrate Judge's Order and AII's overstatement of the issue. ECF No. 309, at 5-6; ECF No. 331, at 23. In contrast to Plaintiff's prior arguments, Northwell's Motion provides extensive detail about (1) the specific IRB process that applied to the Research Study; (2) the

representations Dr. Moline made as part of that process; (3) the chilling effects on both the medical community and the IRB process at issue; and (4) Dr. Moline's view of the need for protection through her affidavit. ECF No. 265, at 7-10. This discussion goes significantly beyond Plaintiff's prior arguments, and Northwell offers an important and unique perspective in this matter in light of its status as a health care provider and its operation of an IRB.

II. The Magistrate Judge's Denial of Northwell's Request for Extension of the Protective Order Was Clearly Erroneous

A. The Protections that Northwell Seeks are Narrowly Tailored and Critical

The protections that Northwell has continually sought in this matter are narrowly tailored and based on well-established protections grounded in the Common Rule and Northwell's IRB process. Northwell has moved this Court to solely prevent Defendants' counsels from questioning Dr. Moline about Plaintiff's identity as a research subject in the Research Study. Northwell takes no position on whether and to what extent Dr. Moline can be questioned about the Research Study and the possible causes of Plaintiff's medical condition—apart from Northwell's request to preclude specific questions surrounding Plaintiff's status as a research subject in the Research Study. ECF Nos. 265, 284, 318. As such, AII's Response has grossly misstated the extremely limited nature of Northwell's request for extension of the Protective Order. ECF No. 331, at 18-19.

As set forth in more detail in Section II.B, *infra*, given the narrowly-tailored nature of Northwell's request and its critical interests in protecting research subject confidentiality, the Magistrate Judge erred under Fed. R. Civ. P. 26(c) in balancing Northwell's interests in extending the Protective Order against Defendants' interests, which are solely rooted in litigation tactics.

i. The Common Rule and Northwell's IRB compel Dr. Moline to keep the identities of research subjects confidential, and Northwell's interests in protecting Plaintiff's identity as a research subject significantly outweigh any interests Defendants have in destroying these IRB confidentiality protections.

The IRB process—firmly grounded in and established by the Common Rule—requires health care institutions to protect the confidentiality of research subjects in human subject research studies. *See* 45 C.F.R. § 46.101. Northwell approved the Research Study through expedited IRB review, which is only appropriate in limited circumstances, including—as pertinent here—for certain categories of research where the IRB review determines that the study does not involve "more than minimal risk" to privacy. *Id.* at §46.110(b)(1)(i). In other words, expedited review is triggered when "reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal." 63 Fed. Reg. 60365 (Nov. 9, 1998).

The Research Study was eligible for consideration of expedited review because it was "research involving materials (data, documents, records, or specimens) that have been collected … solely for non-research purposes (such as medical treatment or diagnosis)." *Id.* at 60366. Northwell's IRB approved the Research Study because Dr. Moline expressly represented in her application for expedited review that (1) she took confidentiality seriously and would take extensive measures to protect the participants' identities; (2) no patient identifiers would be included in research-related summaries; (3) all PHI included in the Research Study would be de-identified; (4) and the PHI would be stored in Northwell's secure database. ECF No. 265, Ex. A. In other words, the Northwell IRB determined that there was "no more than minimal risk" to research subject privacy through the Research Study based on Dr. Moline's representations.

The Magistrate Judge's Order erroneously assigned greater weight to AII's litigation interests than to the confidentiality expectations of the Common Rule and Northwell's related

obligations to protect the identities of research subjects. The only interest that AII has set forth in opposing the Motion is AII's allegation that Plaintiff's status as a research subject could call into question assertions made about Plaintiff's prior exposure to asbestos. ECF No. 197, at 11. Such a position is nonsensical.

Plaintiff's participation in the Research Study does not change Plaintiff's exposure to asbestos through talc, nor does it change whether she was or was not exposed to occupational asbestos. The modification of the Protective Order that Northwell seeks does not prevent Defendants from obtaining any medical records or other relevant history regarding Plaintiff. Nor is Northwell seeking to limit Defendants from attempting to impeach Dr. Moline. Relatedly, the extended Protective Order would not bar any questions to Dr. Moline regarding her knowledge of whether or not Plaintiff had prior exposure to occupational asbestos, or any other aspects of the Plaintiff's medical history. Instead, Northwell only seeks to protect Plaintiff's identity as a research subject of the Research Study.

The Magistrate Judge erred in determining that Defendants' ill-defined litigation interests outweigh Northwell's interests in preserving bedrock IRB-related confidentiality guarantees. ECF No. 309, at 6.

ii. IRB confidentiality protections surrounding Plaintiff's identity continue even though she is deceased and sued Defendants.

Both the Magistrate Judge and AII erroneously state that Dr. Moline's responsibility to protect Plaintiff's identity as a research subject is somehow terminated because Plaintiff was deceased at the time Dr. Moline secured IRB approval. ECF No. 309, at 7 n.2, ECF No. 331, at 32-33. This position misconstrues and inappropriately narrows the confidentiality protections

triggered by IRB approval.[2] Dr. Moline did not apply for and secure IRB approval surrounding a research study involving Plaintiff alone. Instead, she did so for a research study involving thirty-two (32) other individuals, at least twenty-three (23) of who were living at the time. ECF No. 274, Ex. A; ECF No. 265, Ex. A. In other words, the confidentiality protections required by Northwell's IRB, as well as Dr. Moline's confidentiality guarantees in securing IRB approval, were for the entire Research Study. *See* ECF No. 265, Ex. A. This reality is consistent with the fact that the IRB reviews unified protocols holistically and its approvals are correspondingly applied holistically to the research studies themselves—the protocols do not apply to certain research subjects in some situations, and to other research subjects in other situations. *See* 45 C.F.R. § 46.101. Neither the Magistrate Judge nor AII cite any authority supporting the application of different levels of confidentiality protections as between research subjects in an IRB-approved study based on the existence of litigation involving a subset of subjects.

To allow courts or parties to arbitrarily remove or apply IRB protections to certain research subjects that were originally applied by the IRB throughout the study as a result of a Common Rule-compliant process, simply for the sake of litigation, would eviscerate the confidentiality protections paramount to human subjects research. Such a situation would also create untenable situations—*like this one*—where researchers, such as Dr. Moline, are forced to choose between violating confidentiality guarantees in IRB-approved research studies by unmasking the identities of certain research subjects in litigation (while protecting the identities of others) and responding

[2] *See* NIH, "Guidelines for Reviewers: Protections for Human Subjects Review Criterion," https://grants.nih.gov/grants/peer/guidelines_general/Guidelines_for_the_Review_of_the_Human_Subjects.pdf, at 4 (March 18, 2019). *See also* Univ. of Pitt., "Research on Deceased Individuals," https://www.hrpo.pitt.edu/policies-and-procedures/research-deceased-individuals ("Research involving deceased individuals … does not require IRB oversight unless the research involves both living and deceased individuals.").

to deposition questions under oath. ECF No. 265, Ex. A ("Indeed, to date, I have not disclosed the identities of the research subjects in the Article. For example, when I was deposed in a separate but related case in January 2020, I refused to disclose Plaintiff's identity in response to questions from counsel for" AII).

Similarly, the Magistrate Judge and AII have clearly erred in making the unsupported assertion that IRB confidentiality protections are somehow terminated merely because Plaintiff has sued and placed her medical history at issue in the case. ECF No. 309, at 7-8; ECF No. 331, at 30. Plaintiff's participation in an IRB-approved research study is a fundamentally separate issue from a lawsuit that involves Plaintiff's medical history. For example, the fact that Plaintiff's executor signed a Health Insurance Portability and Accountability Act ("HIPAA") release authorizing disclosure of Plaintiff's "medical information" does not, and should not, encompass a research study involving thirty-three (33) participants that is not a part of Plaintiff's medical record. ECF No. 309, at 8. Indeed, nowhere in the Plaintiff's executor's HIPAA release is the Research Study or records tied to Northwell's IRB included as a requested item. *See* ECF No. 179, Ex. F. The case law the Magistrate Judge relies upon in the Order is entirely inapposite as it relates to patients who had expressly consented to disclosure of information tied to the study at issue—no such express consent to disclose the Research Study occurred here. ECF No. 309, at 7.

iii. AII's arguments that IRB approval was not required are incorrect and red herrings—IRB approval was sought and approved.

AII argues that IRB approval was not required for the Research Study because Plaintiff was deceased before Dr. Moline obtained IRB approval and the information in the Research Study was allegedly "public." ECF No. 331, at 30-33. Both positions are incorrect. As set forth in Section II.B.ii, *supra*, IRB approval was required for the Research Study because, *inter alia*, the vast majority of the thirty-three (33) research subjects were living at the time of IRB approval.

AII's citation to language from unrelated studies, at unrelated institutions, and authored by different authors (or different lead authors) has no relevance to the Research Study or Northwell's IRB process. ECF No. 331, at 32. Tellingly, the article that AII emphasizes is distinguishable on its face, as the language AII quotes demonstrates that that study involved "no identifying information" and IRB approval, therefore, was not required. *Id.*

AII also makes the blanket statement that the Research Study was "public" given that the cases were referred to Dr. Moline for medico-legal evaluation. *Id.* at 31. However, AII offers no support as to why such a referral would render the identities of the Research Study subjects (clearly not published in Dr. Moline's peer-reviewed article) otherwise public. Regardless, the fact remains that the Research Study was introduced to Northwell's IRB for review and approval. Northwell granted IRB approval based on the representations Dr. Moline made that the Research Study would protect confidentiality, including through subject anonymity. ECF No. 265, Ex. A. As a result of Northwell's IRB approval, the confidentiality protections and protocols inherent in the Common Rule and Northwell's IRB attached to the Research Study—protections and protocols to which Dr. Moline agreed to abide.[3]

B. The Magistrate Judge's Order Will Have a Chilling Effect on Expedited IRB Review

As argued extensively in Northwell's briefing, allowing anonymous information covered under IRB protocols to become public would undermine the confidentiality protections secured by the Common Rule and IRB principles, resulting in a chilling effect on the IRB process and the willingness of researchers and research subjects to participate in critical studies. ECF Nos. 265,

[3] AII makes sweeping allegations that Dr. Moline engaged in misrepresentations surrounding the Research Study. These allegations relate to the creditability of Dr. Moline's testimony, are outside of the scope of Northwell's Motion, and Northwell does not take a position on them.

284, 318. Indeed, such a chilling effect could have the potential to impede the development of life-saving medical breakthroughs, particularly making research institutions less inclined to grant expedited IRB approval. ECF No. 265, at 8.

The Magistrate Judge correctly articulated Northwell's argument and the central issue in the Order, but failed to assign the position the substantial weight it requires. Specifically, the Magistrate Judge maintained, "Northwell says, if confidential information used by Dr. Moline is discoverable, the risk to privacy of participation in virtually any research study may be more than 'minimal.'" ECF No. 309, at 7. The Magistrate Judge added, "[i]f this is the case, the IRB expedited review process would become essentially a dead letter, forcing all research into a slower, costlier process of approval." *Id.* Despite articulating the heart of the issue, the Magistrate Judge erred by maintaining that Plaintiff allegedly waived confidentiality over the Research Study by filing the present lawsuit. As noted above, there is no support for such a waiver and the case law the Order cites is inapposite.

III. AII Should be Denied Costs

AII is apparently requesting costs associated with filing its Response to Northwell's Objections. ECF No. 331, at 34. AII provides no justification for any such costs, nor is it clear what "costs" AII believes it is entitled. Likewise, AII cites to no authority supporting this demand. A district court may assess fees and costs when a movant has "acted in bad faith, vexatiously, wantonly, or for oppressive reasons." *Hall v. Cole*, 412 U.S. 1, 5, 93 S.Ct. 1943, 1946 (1973). This power must be "exercised with restraint and discretion," *Chambers v. Nasco, Inc.*, 501 U.S. 32, 44–45, 11 S.Ct. 2123, 2132–33 (1991), and is based on whether there was "serious and studied disregard for the orderly process of justice." *Williams v. Giant Eagle Markets, Inc*., 883 F.2d 1184, 1191 (3rd Cir. 1989).

Through its Motion and Objections, Northwell seeks to ensure that its interest in protecting the integrity of its IRB process is maintained, and that the confidentiality associated with that IRB process—including Northwell's fundamental duties to protect research subject privacy—is not lost as a result of an inadvertent disclosure of research study information. AII's implication that such an effort is in bad faith or somehow for an improper purpose is devoid of any degree of merit or legitimacy. AII's request should be denied.

IV. The Sealing Orders

AII argues that the Court should vacate the temporary sealing orders surrounding the Protective Order briefing. ECF No. 331, at 24-26. Northwell incorporates herein by reference its prior arguments supporting a seal. As such, if the Court were to grant Northwell's Objections, the briefing should remain under seal. If the Court were to deny Northwell's Objections, Northwell leaves the sealing issue to the sound discretion of the Court.

CONCLUSION

Northwell respectfully requests that the Court overturn the Magistrate Judge's Order and grant Northwell's Motion. In the alternative, Northwell respectfully requests that the Court remand the Motion to the Magistrate Judge for a hearing on the merits.

This the 8th day of April, 2021.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on April 8, 2021, the foregoing Reply was filed via ECF filing, which will serve all counsel of record in the above-referenced matter.

This the 8th day of April, 2021.

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